IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

In re Heparin Products Liability Litigation, Case No. 1:08-hc-60000

MDL 1953

Pending is a motion by the Baxter defendants for a protective order. (Doc. 272).[1]

Defendants' motion seeks to bar discovery relating to: 1) Xetamol; 2) Propofol; and 3) the Colleague pump. I agree that discovery should not be permitted with regard to Xetamol and Propofol; but I conclude discovery can proceed with regard to the Colleague pump.

Xetamol is not on the market. In any event, as I understand plaintiffs' position, they eschew wanting to learn about that product. So that part of the defendants' motion is moot.

Baxter does not manufacture Propofol. It distributes the drug, which Teva Parenteral Medicines produces. Plaintiffs represent, however, and Baxter does not dispute, that a Las Vegas, Nevada, jury returned a judgment, including an award of $500 million in punitive damages, against Teva and Baxter and in favor of a plaintiff who contracted Hepatitis C after being administered an injection of Propofol.

[1] Defendants filed their motion concurrently in the state cases pending in the Circuit Court of Cook County, Illinois. Judge Duncan-Brice granted Baxter's motion in part and denied it in part.

Plaintiffs seek discovery about Baxter's quality control procedures as to Propofol in light of that judgment. They contend, at least implicitly, that Baxter's quality control processes broke down or otherwise didn't work, and thus contributed to Baxter's exposure to liability in that case.

Baxter contends, and again, plaintiffs don't dispute, that the plaintiff in the Las Vegas case became infected with Hepatitis C because the Propofol injection was with a contaminated needle, previously used on another, presumably diseased individual.

According to plaintiffs, Baxter should have foreseen the risk that contaminated needles might be used to give injections from multi-dose units, rather than in single-dose units.[2]

The manner in which Baxter distributed Heparin is not at issue here. Plaintiffs do not contend that how Baxter packaged Heparin is related to its contaminated condition. Plaintiffs likewise do not contend that, prior to starting to ship the contaminated Heparin, Baxter was aware of the risks that it posed to patients who would be receiving it.

Indeed, even after adverse incident reports put Baxter on notice that Heparin appeared to be causing undesired and possibly severely injurious consequences, the fact of contamination with OSCS was far from readily apparent.

When Baxter knew or should have known about the contamination and its risks may be issues in this MDL. But, unlike the situation regarding Propofol, plaintiffs here are not claiming that Baxter was on notice from the outset (as I assume the plaintiff in the Las Vegas case contended) about the risks that its product would be creating. Plaintiffs do not contend that Baxter should have

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[2] I note some doubt about the logic of plaintiff's contention. If the person giving injections is using a contaminated needle, why wouldn't he or she do so whether pulling the drug from a multi- or single dose source? But I need not call on plaintiffs to answer that question, as I agree with Baxter that in any event, discovery should not be allowed with regard to Propofol.

been doing something before it began distributing the contaminated Heparin to determine whether it was contaminated.

At issue here, rather is, *inter alia*, the adequacy of Baxter's *post hoc* response. To the extent that is a "quality control" issue, or set of issues, it bears no relationship to what the Las Vegas plaintiff claimed Baxter should have foreseen and done before shipping Propofol. The only similarity between the two circumstances is that some third party played a role in the infection, with regard to Propofol, and the contamination, with regard to Heparin.

This is not a sufficient nexus, under all the circumstances in both situations, to allow discovery about Baxter's quality control processes with regard to Propofol.

With regard to the Colleague pump, plaintiffs appear to desire discovery about Baxter's noncompliance with a consent decree and failure to implement a fully effective recall after problems arose with that device.

I see two issues. First, plaintiff's contend that they need that discovery to prepare an anticipatory response to evidence that Baxter might offer at trial that it puts patient safety first and has effective and efficient systems for ensuring patient safety. If Baxter were stating that it was not intending to present such evidence at trial, that would moot the need to permit discovery on that basis. But so far Baxter has not done so. That being so, the discovery appears appropriate.

In any event, there is another basis on which the desired discovery can proceed. In this case plaintiffs claim that Baxter's recall notices provided inadequate notice to those who received the notices and, in any event, not every entity and individual who should have received those notices got them. As a result, plaintiffs contend, Baxter's recall efforts failed to be as effective as they needed to be to ensure, or least reasonably ensure, that no patient would thereafter receive contaminated Heparin.

As I understand the developments with regard to the Colleague pump, they involved, at least in part, the efficacy of Baxter's recall procedures. That being so, there is a nexus, at least for purposes of pretrial discovery, between the procedures with regard to that device and those implemented with regard to the contaminated Heparin.

Like Judge Duncan-Brice, albeit in a less scholarly manner and perhaps for somewhat different reasons, I conclude that the plaintiffs are entitled to discovery with regard to the Colleague pump—at least with regard to issues relating to recalls.

It is, therefore,

ORDERED THAT defendants' motion for a protective order (Doc. 272) be granted in part and denied in part, as provided herein.

So ordered.

s/James G. Carr
United States District Judge